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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,228	11/05/2003	Michael R. Slater	341.030US1	8004
21186 7590 09/19/2007 SCHWEGMAN, LUNDBERG & WOESSNER, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			EXAMINER VOGEL, NANCY S	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 09/19/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/702,228	Applicant(s) SLATER ET AL.	
	Examiner Nancy T. Vogel	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 13-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/2/07, 8/29/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1-67 are pending in the case.

Claims 13-67 are withdrawn.

Receipt of Information Disclosure Statements on 7/2/07 and 8/29/07 is acknowledged.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-7 rejected under 35 U.S.C. 102(b) as being anticipated by Bilcock et al. (previously cited) and BCCM-BCCM/LMBP plasmids catalogue ([bccm.be.sp.be/db/lmbp\\_plasmid\\_details.php?NM=pAT153](http://bccm.be.sp.be/db/lmbp_plasmid_details.php?NM=pAT153) website) (cited for informational purposes only).

Bilcock et al. disclose vectors comprising a first restriction enzyme site that generates a 3' end, which is 5' to a recognition site for a second restriction enzyme which generates blunt ends. The second restriction enzyme which generates blunt ends may be a site such as SspI, SrfI, Scal, SapI, EcoRV, etc. (see attached map of pAT153, from which pDB8 is constructed), all of which generate blunt ends. Further, enzymes such as AluI that generate blunt ends, and which recognize 4 nucleotides, are frequent in the plasmid of Bilcock et al. and would be expected to be 3' to one of the SgfI site. Furthermore, it is noted that since there are two SgfI and SrfI sites in pDB8, as

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applicants note, it is maintained that at least one of the Sgfl sites generates a 3'TA overhang that is 5' to at least one of the SrfI sites. There is no requirement in the claims that only one of each of these first and second recognition sites are in the vector.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as originally filed does not provide support for the invention as now claimed: of "wherein the site in the recombinant vector formed by ligation of the 3'TA overhang and the end generated by Sgfl is 5' to the open reading frame, and wherein if the vector backbone has an open reading frame that is 5' to the site and is in frame with the open reading frame 3' to the site, the vector backbone includes a promoter that is operably linked to the open reading frame which is 5' to the site". This is a new matter rejection. The specification does not provide sufficient landmarks nor

direction for the instant methods encompassing the above-mentioned limitations, as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

This rejection is maintained essentially for the reasons set forth in the previous Office action, mailed 4/5/07.

Applicant's arguments filed 7/2/07 have been considered but have not been found convincing. Applicants have stated that Figures 14-16 and particular lines in the specification provide support for the recitation in claim 1. However, and examination of these sections does not find such support. Therefore, the rejection is maintained.

Claims 10-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained essentially for the reasons set forth in the previous Office action, mailed 4/5/07.

Applicant's arguments filed 7/2/07 have been considered but have not been found convincing. Applicants have argued that regarding the recitation of "X1-X3", etc.,

a standard textbook discloses "every codon including stop codons". However, it is acknowledged that stop codons are known in the art. However, the rejection was based on a lack of written description of those enzyme sites, which, when linked, would generate the recited nucleic acid sequences. Therefore, the rejection is maintained.

The following is a new rejection:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1- 12 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in the recitation of "if the vector backbone has an open reading frame that is 5' to the site and is in frame with the open reading frame 3' to the site, the vector backbone includes a promoter that is operably linked to the open reading frame which is 5' to the site" since it is not clear what "site" is being referred to.

### ***Conclusion***

No claims are allowed.

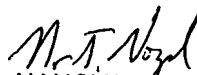
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NTV  
9/14/07

  
NANCY VOGEL  
PRIMARY EXAMINER